

REMARKS

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view the remarks herewith.

• **Status of the Claims and Restriction/Election Requirements**

Claims 1-27 are pending in this application.

Claims 12-21, 24 and 25 are currently amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter has been introduced. Support for the amendments can be found throughout the specification.

The Restriction Requirement of May 26, 2005, restricts claims 1-11, 22, 23, 26 and 27 to the following groups of inventions:

- I. Claims 1-11 and 22, drawn to a method for delivering a genetically modified bacterium comprising a heterologous gene encoding for a protein having antitumor activity, classifiable in class 424, subclass 93.2.
- II. Claim 23 drawn to a DNA having a nucleotide sequence of SEQ ID NO:1, classifiable in class 536, subclass 23.7.
- III. Claims 26 and 27, drawn to an anaerobic bacterium belonging to the genus *Bifidobacterium*, classifiable in class 424, subclass 234.1.

Further in the event that Applicants elect Group I, the Restriction Requirement states that a species also be elected. Specifically, these species are: (1) DNA coding for a protein having an anti-tumor activity, or (2) DNA coding for a protein having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance, as in instant claim 4. Applicants hereby elect Group I and the species of DNA coding for a protein having an anti-tumor activity. This election is made with traverse. Applicants reserve the right to file divisional applications to non-elected subject matter.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

Group I is directed to a method of delivering a genetically modified bacterium and Group III is directed to an anaerobic bacterium belonging to the genus *Bifidobacterium*. It is respectfully submitted that any search for the bacterium of the Group I claims will certainly encompass references for the bacterium of the Group III claims. The two groups are inextricably linked in that the claims of both groups contain an anaerobic bacterium belonging to the genus *Bifidobacterium*. Furthermore, all of the claims are classified in class 424. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine the two groups together, as a search for the method of delivering a genetically modified bacterium of Group I would necessarily include the bacterium of Group III. Finally, Group II is directed to the nucleotide sequence of the HU gene, from *Bifidobacterium longum*. As Group III is directed to an anaerobic bacterium belonging to the genus *Bifidobacterium*, a search for the bacterium of Group III would also reveal sequence information pertaining to the nucleotide sequence as claimed in Group II.

Claim 1-3 are generic claims. Claim 4, which depends from claims 1-3, lists as a Markush group two types of DNA molecules. The Examiner is respectfully requested to review M.P.E.P. § 803.02 which states “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.” Furthermore, in view of M.P.E.P. § 803, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants’ claims are directed to methods of delivering a gene wherein the delivered DNA codes for a protein having an anti-tumor activity or DNA coding for a protein having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance. Consequently, there is a disclosed relationship between the species as they all code for proteins that affect tumors.

Additionally, the claims are not broken into separate classifications on the basis of which species is claimed. Consequently, it can be assumed that the classification of all the claims into a

single group was made considering each of the species, such that the search of any species would be co-extensive and include the remaining species.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

- **Formal Matters**

Claims 12-21, 24 and 25 were objected under 37 CFR 1.75 (c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Accordingly, claims 12-21, 24 and 25 were not further treated on the merits.

The current Amendment clarifies the alleged improper format of the claims by removing the multiple dependencies of claims 12-21, 24 and 25. The subject matter of these claims is related to the subject matter of claims 1-11, 23, 26 and 27 which are subject to the current restriction/election requirement. The claims as originally filed and presented herein, represent a web of knowledge and continuity of effort that merits their examination as a single application. Therefore, the Applicants respectfully request withdrawal or at least modification of the current restriction/election requirement to include the claims not considered previously.

CONCLUSION

In summary, enforcing a restriction requirement that excludes currently amended claims 12-21, 24 and 25 from consideration would pose an undue burden on the Applicants. Accordingly, in view of the foregoing, reconsideration and withdrawal, or at least modification, of the restriction requirement to consider the subject matter of claims 12-21, 24 and 25 are respectfully requested.

Respectfully submitted,
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